Attachment 9



Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images

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- Pursuant to its responsibilities under the Tobacco Control Act, FDA's Center for Tobacco Products (CTP) is conducting studies that build on prior research to gain insight on consumer comprehension, perceptions, and reactions to cigarette graphic health warning images. This focus group project is a component of that research.
- The knowledge gained from these groups will be used to refine the image element of warnings that will eventually be paired with text warning statements.

RESEARCH QUESTIONS

- 1. What information do the images alone convey to consumers? What information do people take away from the image?
- 2. Which images convey the clearest information to consumers about the health consequences of cigarette smoking?
- 3. Which image statement parings convey the clearest information to consumers about the health consequences of cigarette smoking?
- 4. Does each image accurately depict the health consequence of smoking described in its paired warning statement?
- 5. Are the people/organs/conditions depicted in each image believable/realistic?
- 6. How do the images aid in comprehension/understanding of the health effect of smoking beyond the statement alone?
- 7. In instances where there are multiple images for the same health condition, which image/statement pairing provides the clearest information to consumers?
- 8. Which image/statement pairings give participants new information they didn't know before?

Procedures:

Participant Recruitment

- Subcontracted facilities in each location recruited participants by telephone from their existing databases using screeners (adult and youth).
- Before speaking with youth, facilities obtained consent to screen from parent. Youth were asked to complete
 screening in a private location. Individual responses to screener questions were not shared with parents. Qualified
 youth were required to bring a signed parent permission form to the facility in order to participate.
- All participants, upon arrival at the facilities, signed a consent (adult) or assent (youth) form and were given a copy
 of the form.
- Participants were paid an incentive at the conclusion of each focus group.

Focus Group Discussion

- Each focus group lasted up to 90 minutes and was led by a trained moderator (n=2) using a semi-structured moderator guide.
- Participants were given a "Participant Booklet" containing images and image/statement pairings to be discussed in the group. Each image was sized to be 55mm wide x 42mm tall (the actual size they would be on a pack of cigarettes). There were 4 unique booklets, each comprising a subset of health topics. Each booklet was used in 5 groups and was used in each city at least once. At the end of each booklet was an "Individual Worksheet" spanning all health topics that contained all images and image/statement pairings for which there were multiple pairings.
- For each health topic, participants first answered questions about the image alone, followed by the image/statement pairings. When there were multiple images per statement, participants were asked to circle the image that goes best with the statement in their booklets. At the end of the discussion, participants completed the "Individual Worksheet" and discussed their answers.
- Groups were audio recorded and video streamed and notes taken for each group.
- Audio recordings were transcribed.

Harms Child 6:20 mage A Document 34-12 Filed 05/15/20 Page 6 of 22 PageID #: 1435

General Responses

- Most participants understood that this image was a sick child with a breathing problem.
 - Participants mentioned that the child had difficulty breathing (asthma, breathing complications, wheezing).
- A common theme was the effects of secondhand smoke.



Δ

Is there anything confusing about the image? Is the image realistic?

- Some participants stated that it was unclear what was wrong with the child. Without additional information, participants would not know that the image is associated with smoking.
- Most participants thought the image was clear and realistic, although some said it was not.
 - It could be realistic because there are a lot of different breathing problems associated with smoking.
 - Reasons it was not realistic were: the child appeared to be too young to be so sick; the image didn't look natural (it looked drawn or photoshopped, especially the tube and mask); eyes were not red enough.

Suggestions for improvement

Make the tube to the mask look more realistic vs. drawn on.

General Responses

- Participants had a variety of opinions about what the image was showing, including that the girl was coughing, sneezing or crying.
- Participants noted that the child appears to be sick and is wearing a hospital gown, although not all participants identified her clothing as a hospital gown.
- Less common interpretations were that the child was singing into a microphone or that she was dirty.

Is there anything confusing about the image? Is the image realistic?

- It was unclear if the child was sick, yawning, coughing from choking on water, if she tasted something bad or was upset about something.
- Participants had mixed opinions about whether the image was realistic.
 - Lack of a background makes the image look unrealistic. The image appears to be exaggerated or staged. The girl's body is not proportional (her hand is big) and she looks older than a toddler.

Suggestions for improvement

- Make it more clear that she is coughing and wearing a hospital gown.
- Make the girl's body more proportional (make the hand smaller).
- Make the girl look younger.



В

Harms Child 6:20 Tobacco smoke can harm your children 1437

Which image goes best with the statement?

83.3%



16.7%



B1

- Most participants stated that A1 was the best pairing. Reasons for choosing A1 included:
 - A1 can more easily be related to smoking.
 - A1 conveys the severity better (the mask, dark circles under his eyes and pale skin do this).
 - Although B1 shows discomfort, it's not clear if there would be lasting damage.
 - In B1, it's not clear that the child is wearing a hospital gown.
- Reasons for choosing B1 included:
 - The child in B1 appears to be in more pain/distress.
 - A1 is not a realistic outcome of secondhand smoke, whereas coughing is

Which pairing best helps you understand the relationship between smoking and harm to children?

 Most participants chose A1 because it shows more serious harm, although a few participants said that B1 was more realistic.

^{*} Results are from 42 participants in 5 groups.

Harms Babies 20-cv mage Document 34-12 Filed 05/15/20 Page 9 of 22 PageID #: 1438

General Responses

 The most common interpretation of the image was that it was a lowbirth-weight or premature baby.



D

Is there anything confusing about the image? Is the image realistic?

- Participants thought this image looked realistic overall.
 - However, many participants noted that the baby looked bigger than 4 lbs., noting that the baby looked healthy and normal.
- Males in a youth smoker group did not know that 4 lbs. was small for a baby.

Suggestions for improvement

- A few participants noted the number on the scale could be larger to be more noticeable.
- Making the baby smaller on the scale would make it look more realistic.

Harms Babies - Smoking during pregnancy causes premature birth

Does the sentence help you understand what the picture is?

- Overall, participants said the sentence confirms what they thought the picture is.
- Some participants noted that the sentence is not necessary because the image is so obvious.

WARNING: Smoking during pregnancy causes premature birth.



C5

Do the sentence and picture together teach you anything about the relationship between smoking and harm to babies?

- Overall, participants stated the information in the sentence was not new information to them.
- A few participants in two groups knew smoking while pregnant was harmful to the baby, but did not specifically know it could cause premature birth.

Harms Babies - Smoking during pregnancy stunts fetal growth

Does the sentence help you understand what the picture is?

- Overall, participants said the sentence helped them understand what the picture is.
- Participants in one group discussed that the sentence did not help them understand what the picture is.
 - One participant said the phrase "stunts fetal growth" made them wonder if this was a week-old baby that is not gaining weight like it should or if it was an infant.
 - One participant said the picture does not tell you the baby is not healthy.

Do the sentence and picture together teach you anything about the relationship between smoking and harm to babies?

- Participants had mixed opinions about whether the sentence and picture together taught them anything new about the relationship between smoking and the harm to babies.
 - A few participants said that most people already know smoking harms babies.
 - A few participants said they did not know smoking actually "stunts" the growth process.



D6

Cancer — 111126e | 00176-JCB | Document 34-12 | Filed 05/15/20 | Page 12 of 22 PageID #: 1441

General Responses

- The most common interpretation of the image was that it was a woman with a tumor.
- A few participants thought there might be multiple tumors or the lump on the woman's neck might be lymph nodes or a goiter.



Is there anything confusing about the image? Is the image realistic?

- Overall, most participants did not identify anything confusing about this image.
- Participants had opinions about whether this image looked realistic.
 - Some participants thought the lump was too large to be realistic. One participant remarked that it was not realistic because a person would have a tumor removed before it became that large.

Suggestions for improvement

Making the lump smaller would make this image more realistic.

Lung Disease²⁰⁻ Cigarettes cause fatal lung disease * 1442

Which image goes best with the statement?

23.8%



73.8%



T13

- Most participants believed that T13 is the best pairing.
 - It makes more sense to show an image of the lungs than someone who is still alive because the topic is "fatal lung disease" ("false advertising").
 - it is about the lung.
- Some participants chose S13. Reasons include:
 - The person in the image makes the message more personal (someone might connect it with someone they know).

Which pairing best helps you understand the relationship between smoking and lung disease?

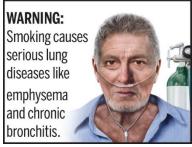
 Overall, participants chose the same image/statement pairing that they chose when determining the best image/statement pairing for this statement.

^{*} Results are from 42 participants in 5 groups. Note: Total does not sum to 100% due to missing data.

Lung Disease Smoking causes serious lung diseases like emphysema and chronic bronchitis

Which image goes best with the statement?

88.1%



S14

11.9%



T14

- Most participants believed that S14 is the best pairing.
 - S14 is more realistic shows how a disease affects a live person.
 - The oxygen machine indicates a chronic, long-term condition; the machine is associated with emphysema and chronic bronchitis.
- Some participants chose T14 because the diseased lung indicated a serious disease.

Which pairing best helps you understand the relationship between smoking and lung disease?

- Most participants believed that S14 helps them understand the relationship.
 - S14 portrays diseases that you might not die from, whereas T14 portrays death.
 - S14 sends the message that you won't necessarily die from smoking right away, but it will affect you for the rest of your life. You could still have irreversible damage. S14 shows an unhappy person, hooked up to the machine, whereas T14 could be anything (e.g. autopsy)...
 - T14 is confusing because two diseases are mentioned while the image shows only one pair of lungs.

^{*} Results are from 42 participants in 5 groups.

Heart Disease O-cv Mage Ocument 34-12 Filed 05/15/20 Page 15 of 22 PageID #: 1444

General Responses

- The most common theme was that the man had open heart surgery.
 A transplant was mentioned.
- One participant said the man might have had a lung transplant.
- Participants mentioned the purpose of the tubes:
 - to "suck up the blood"
 - · to feed him something
 - to pump the blood

Is there anything confusing about the image? Is the image realistic?

- Many participants were confused about the scar and the tubes and what type of surgery they indicate.
- Most participants thought the image was realistic, however there were some exceptions:
 - the shading for the tubes is not quite right
 - the man would unlikely be able to stand immediately after surgery
 - the tubes do not seem to be appropriate

Suggestions for improvement

The image would be more clear if the man's head wasn't cut off.



O

Diabetes Castinage L76-JCB Document 34-12 Filed 05/15/20 Page 16 of 22 PageID #: 1445

General Responses

- All groups brought up that the image shows someone testing for diabetes or doing a blood sugar test.
 - One participant noted that the level was high (should be between 80 and 120).
- All groups discussed the fingernails being yellow, crusty, discolored or dirty.

Is there anything confusing about the image? Is the image realistic?

- Some participants didn't know what the rating ("175") meant (whether
 it was high or low) One participant noted that it does say the blood
 sugar is "above target" but it's hard to read.
- One participant wondered if smoking makes you diabetic.
- A couple of participants (one with type 1 diabetes and one who had gestational diabetes) noted that the level is slightly elevated but not too severe.
- The fingers appeared to be those of an older person, suggesting that the reading on the device could be age related.

Suggestions for improvement

- Make the numbers on the display red or flashing.
- Make the blood look more realistic it's too much blood.
- Possibly have the numbers be higher.



- 1

Peripheral Vascular Disease 44-1 mage 120 Page 17 of 22 PageID #: 1446

General Responses

- Participants had a wide variety of interpretations for this image;
 - Amputation was mentioned as well as "missing toes."
 - Diabetes was mentioned multiple times.
 - Clogged arteries and not enough blood flow to the feet can cause limbs to fall off.
 - One participant hypothesized that it was a disease you could get from smoking.
 - Gangrene; Rotting feet
 - Infections
 - Frostbite
 - Gout

Is there anything confusing about the image? Is the image realistic?

- The cause of the foot problem is unclear.
 - A few participants wondered why the feet are black.
 - The image is confusing on its own.
 - The connection to smoking is not clear.
- Participants had mixed opinions on whether the image was realistic.
 - It seemed realistic to some but too dramatic, which makes it less credible.
 - People might not be able to relate to it because it is extreme.
 - The lighting on the upper right leg and the excessive redness on the toe make it less realistic.

Suggestions for improvement

 Make the image appear less severe. Change the lighting on the upper left leg and the excessive redness on the toe.



E

Peripheral Vascular Disease Smoking reduces blood flow to the limbs, which can require amputation

Does the sentence help you understand what the picture is?

- The words help some participants understand that the toes did not fall off, but were surgically removed.
- Some participants were still confused about why some toes were missing and some were black or red.
- The word "limbs" is confusing to some participants because they think of "limbs" as arms and legs.
- One participant mentioned that it should focus on "prolonged smoking" rather than just "smoking."

Do the sentence and picture together teach you anything about the relationship between smoking and amputation (peripheral vascular disease)?

- That smoking reduces blood flow to the limbs, which can require amputation, is new information for many participants. The idea of losing limbs scares some participants and grabs their attention.
- Some participants knew that smoking clogged arteries or reduced blood flow, but not to this extent.



E7

Sexual Dysfunction 6-3 Overview Filed 05/15/20 Page 19 of 22 Page ID #: 1448

Segments (n=42)

- 1 older adult group (n=10)
- 2 younger adult groups (n=17)
- 1 youth susceptible group (n=5)
- 1 youth smoker group (n=10)



WARNING:
Smoking
reduces
blood flow,
which can
cause erectile
dysfunction.

Sexual Dysfunction 6-JCB maget 4-12 Filed 05/15/20 Page 20 of 22 PageID #: 1449

General Responses

- Participants had a wide variety of interpretations for this image.
 - Erectile dysfunction, inability to have sex and/or "blood flow problem" were mentioned in 4 of the 5 groups.
 - The couple could have a strained relationship. One participant thought conflict could be caused because he smokes and she doesn't.
 - The woman is in "la la land."
 - Addiction could be involved.
 - Insomnia/sleeplessness
 - Stress/depression
 - In one group participants discussed the fact that the man looks older than the woman. This could be due to smoking.

Is there anything confusing about the image? Is the image realistic?

- Many participants agreed that without the words, it was difficult to know what the image was depicting.
- Most participants believed the image was realistic, but some thought the image either looked "posed" or had aspects that were unclear.
- It is not clear if the man on the edge of the mattress.
- The color of the man's arms makes him appear burned.
- The man's arm looks like a "tentacle."
- The woman's head is in a weird spot.



F

Sexual Dysfunction 6-JC Image 17-(2) Filed 05/15/20 Page 21 of 22 PageID #: 1450

Suggestions for improvement

- Have a younger man in this image instead of the man depicted or have the woman appear to be older.
- Change the coloring on the man's arms (they appear burned).
- Make the man's arm look more normal (looks like a "tentacle").
- Change the relative location of various items (e.g. man does not appear to be on edge of bed; the woman's head is in a strange location).
- Do not show man's crotch ("awkward").
- Try to make the image look less "posed."



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Sexual Dysfunction - Smoking reduces blood flow, which can cause erectile dysfunction

Does the sentence help you understand what the picture is?

- Most participants stated that the words helped them understand what the picture was.
 - Some participants stated they were trying to have sex but couldn't.
 - Some participants thought they have been trying to have kids and couldn't.
 - Some participants noted that the couple doesn't have a happy relationship; they appear to be unhappy or upset.

WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.



F8

Do the sentence and picture together teach you anything about the relationship between smoking and sex (sexual dysfunction)?

- Most participants learned something new from this image/statement pairing, including:
 - Smoking can cause erectile dysfunction.
 - Smoking reduces blood flow.
 - Erectile dysfunction can cause problems for the partner.